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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,006	07/16/2003	Gilbert J. Grant	GRANT 1A	7468
1444	7590	07/21/2004	EXAMINER KISHORE, GOLLAMUDI S	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			ART UNIT 1615	PAPER NUMBER

DATE MAILED: 07/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/620,006

Applicant(s)

GRANT ET AL.

Examiner

Gollamudi S Kishore, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims included in the prosecution are 1-10.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 4-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,696,080 in view of Hamaguchi (4,844,904) and Schneider (5,626,832) (both are on record) by themselves or in combination.

The patented claims recite a method of preparation which is similar to instant claimed method differing only in the final washing step. The patented claims recite washing the liposomal composition with water whereas in the claimed process, the washing is performed with hyperosmotic salt solution.

Hamaguchi discloses liposomal formulations in which the osmotic pressure of the external phase is at least 20 percent more than the osmotic pressure of the solution

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used for entrapping the drug in liposomes. The solutions contain sodium chloride.

According to Hamaguchi such liposomes are stable (note the abstract, examples and claims).

Schneider while disclosing liposomal compositions teaches that it is possible to use hypertonic solutions containing salts and glucose as the external medium (note the abstract, col. 7, lines 10-19).

It would have been obvious to one of ordinary skill in the art to use a hyperosmotic saline solution to wash the liposomes since Hamaguchi teaches that such liposomes are stable and Schneider teaches it routine practice in the art.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Legros (5,244,678) in view of Kirby (Biotechnology, 1984) both are of record.

Legros discloses liposomal bupivacaine formulations and a method of providing local anesthetic effect (note the abstract and Example 1). Although Legros's liposomes are prepared by the conventional method of preparation of liposomes, the inventors state that the liposomes can be prepared by any art known method (Example 1).

Kirby discloses a method of preparation of liposomes by dehydration-rehydration method. According to Kirby, the liposomes prepared by this method have several advantages such as the simplicity of the preparation under mild conditions, capability of entrapment of a wide variety of materials in high amounts and the applicability for industrial use (note the abstract and discussion).

The use of the method of Kirby for the encapsulation of bupivacaine taught by Legros would have been obvious to one of ordinary skill in the art because of the advantages of using such a method as taught by Kirby. The criticality of hyperosmotic rehydrating medium is not readily apparent to the examiner in the absence of unexpected results.

3. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Legros (5,244,678) in view of Kirby (Biotechnology, 1984) as set forth above, further in view of Hamaguchi (4,844,904) and Schneider (5,626,832) (also of record) by themselves or in combination.

Legros and Kirby do not specifically teach the use of hyperosmotic solutions.

Hamaguchi discloses liposomal formulations in which the osmotic pressure of the external phase is at least 20 percent more than the osmotic pressure of the solution used for entrapping the drug in liposomes. The solutions contain sodium chloride.

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According to Hamaguchi such liposomes are stable (note the abstract, examples and claims).

Schneider while disclosing liposomal compositions teaches that it is possible to use hypertonic solutions containing salts and glucose as the external medium (note the abstract, col. 7, lines 10-19).

It would have been obvious to one of ordinary skill in the art to use a hyperosmotic saline solution to rehydrate liposomes since Hamaguchi teaches that such liposomes are stable and Schneider teaches it routine practice in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, PhD whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gollamudi S Kishore, PhD
Primary Examiner
Art Unit 1615

GSK